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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/550,857	04/17/2000	Thomas Buch-Rasmussen	NN 26	1708

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PATENT DEPARTMENT
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EXAMINER	
WARD, PAUL V	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 01/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/550,857	BUCH-RASMUSSEN ET AL.	
	Examiner	Art Unit	
	PAUL V WARD	1623	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *10 December 2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☐ The a)☐ affidavit, b)☐ exhibit, or c)☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *1-7,9-14,16-35,39-55 and 59-88*.

Claim(s) withdrawn from consideration: _____.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Response to Amendment filed December 10, 2004
The rejection under 35 U.S.C. 103 in view of Roser is maintained over Applicants' amended claims because Roser teaches a solid drug delivery system of a defined size and shape (e.g., needle) comprising a therapeutic agent, and a non-crystallization agent. Additionally, Roser discloses that the system can be modified by combining a variety of carbohydrates.

The rejection under 35 U.S.C. 103 over Roser in view of Bar-Shalom is maintained over Applicant's amended claims. As set forth supra, Roser teaches a solid needle-shaped pharmaceutical composition comprising a binder, therapeutic agent, a noncrystallization agent (e.g., sugar alcohols). Roser does not specifically state that the composition be capable of penetrating the cutis or mucosa. However, Bar-Shalom teaches solid pharmaceutical compositions and states that these compositions must have the sufficient strength to enable penetration of the skin or mucosa. Thus, various materials can be added to the compositions, including sugar alcohols, ploysacharides and carbohydrates.

It would have been obvious to one of skill in the art to make and use the compositions of the present invention to make use the parmaceutical compositions of the presnet invention. Roser teaches pharmacuetical compositions comprising all of the disclosed ingredients. Bar-Shalom teaches that such pharmaceutical compositions require only enough binder to give sufficient strength to penetrate the skin. The combination of the therapeutic agent as well as the formulation details are considered to have been obvious over the overall teaching of Roser in view of Bar-Shalom, for the purpose of optimizing the effectiveness of the composition and of minimizing the amount of pain and tissue damages. It would have been obvious to one of skill in the art at the time the invention was filed to modify the particular carbohydrate or combine a variety of different carobydrates to achieve a delivery system that can be molded into any shape or form, inkling a needle, for use in controlled, pulsatile or delayed release of guest substances.

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